

3. 510(k) Summary

Sponsor: Boston Scientific Corporation
160 Knowles Drive
Los Gatos, CA 95032

SEP 20 2006

Contact Person: Sarah Peterson
Phone Number: 763-494-2133
Fax Number: 763-494-2981
Prepared: August 30, 2006

Trade Name: PolarCath™ Peripheral Dilatation System
Common Name: Percutaneous Transluminal Angioplasty Catheter
Classification: II
Product Code: LIT/DQY
21 CFR 870.1250

Predicate Devices: PolarCath Peripheral Dilatation System

Device Description

The PolarCath Peripheral Dilatation System consists of a Catheter, Inflation Unit, connecting cable and a rechargeable battery pack with recharging unit and battery receptacle. The inflation medium (liquid nitrous oxide) is provided in a disposable 14 gram cartridge.

Indications for Use

The PolarCath Peripheral Dilatation System is indicated to dilate stenoses in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene (PTFE) access grafts or arteriovenous dialysis fistulae. The PolarCath Peripheral Dilatation System is also indicated for post-deployed stent expansion of self-expanding peripheral vascular stents.

Substantial Equivalence

The PolarCath Peripheral Dilatation System design, materials, manufacturing process and intended use are substantially equivalent to the predicate device and other marketed PTA catheters.

Performance Data

The safety and effectiveness of the modified PolarCath Peripheral Dilatation System is demonstrated with design control activities and bench testing on file at Boston Scientific.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2006

Boston Scientific, Inc
c/o Ms. Sarah Peterson
Regulatory Affairs Specialist
160 Knowles Drive
Los Gatos, CA 95032

Re: K062594

Trade Name: PolarCath™ Peripheral Dilation System
Regulation Number: 21 CFR 870.1250
Regulation Name: Angioplasty Catheter
Regulatory Class: II (two)
Product Code: DQY, LIT
Dated: August, 2006
Received: September 1, 2006

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Danna R. Vachner

 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. 510(k) Indications for Use

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510(k) Number (if known): K062594

Device Name: PolarCath™ Peripheral Dilatation System

Indications for use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dana R. Vachney
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062594